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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,154	01/17/2002	Howard Milne Chandler	0141-2004	3461

7590

08-06/2004

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,154	Applicant(s) CHANDLER, HOWARD MILNE	
	Examiner Dwayne K Handy	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 1-8 is/are allowed.
 6) ☒ Claim(s) 9-11 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 2, 4-6 and 8 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Kagaya (EP 0727653) in view of Grow et al. (EP 0281251). This rejection has been lifted for these claims in light of applicant's arguments submitted 5/20/2004. Please see Response to Arguments below.

3. Claims 9 and 11 were also previously rejected under 35 U.S.C. 103(a) as being unpatentable over Kagaya (EP 0727653) in view of Grow et al. (EP 0281251). This rejection remains in effect however. Please see Response to Arguments below.

4. Claims 3 and 10 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Kayaga (EP 0727653) in view of Grow et al. (EP 0281251) and further in view of Hori et al. (5,460,781). This rejection has been lifted for method claim 3, but remains for claim 10 drawn to the assay kit. Please see Response to Arguments below.

5. Claim 8 was previously rejected under 35 U.S.C. 103(a) as being unpatentable over Kayaga (EP 0727653) in view of Grow et al. (EP 0281251) and further in view of Schrieber (5,264,181). This rejection has been removed in light of applicant's arguments submitted 5/20/2004.

Response to Arguments

6. Applicant's arguments, filed 5/20/2004, with respect to claims 1-8 drawn to methods of collecting a fluid sample derived from fecal material and detecting blood in fecal matter have been fully considered and are persuasive. The rejection of claims 1-8 has been withdrawn.

7. Applicant's arguments, filed 5/20/2004, with respect to claims 9-11 drawn to the kit have been fully considered but they are not persuasive. In claim 9, applicant has broadly claimed an assay kit for testing fecal matter. The kit is comprised of a sample collection device which is a brush or brush-like and means for detecting an analyte. Applicant has amended claim 9 to include a limitation on the collection device that "a

fluid sample may be collected within the bristles of the brush or brush-like device". This limitation, however, appears to be drawn to an intended use of the brush instead of the actual structure of the brush ("....may be collected within the bristles...."). Therefore, the Examiner believes the combination of the references "Kayaga" and "Grow" still meet the limitations of claim 9. As stated in the previous rejection, Kayaga teaches a device for sampling feces which has a brush element and a collection container. Grow teaches methods for testing fecal samples and includes the reagents to do so. One would add the reagents from Grow to the device of Kayaga to perform tests on collected fecal samples. The combination of the two references, then, provides all the elements of the kit of claim 9. The fact that Kayaga does not collect the sample as a fluid sample is a spurious argument for the **kit claims** since the particulars of the claimed kit do not require the collection of a fluid sample in the manner that the method claims require it.

As for the addition of the reference Hori to the teachings of Grow and Kayaga in the rejection of claim 10, applicant has argued Hori does not add any teachings since Hori does not teach a brush as the collection tool. The Examiner respectfully disagrees. The addition of Hori involves the addition of brush dimensions, not the brush element itself. This was put forth by the Examiner on page 4, paragraph 4 of the previous Office Action. Hori teaches a fecal sampler with fibers that extend 5-7 mm in length. Hori also teaches that this dimension is convenient for sampling and capturing occult hemoglobin. The Examiner considers the Hori reference to be analogous art since both Hori and Kayaga teach collection tools for collecting fecal matter.

Allowable Subject Matter

8. Claims 1-8 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter. In claim 1 applicant has claimed a method of collecting a sample from fecal material comprised of the steps of contacting the fecal material with a fluid and then ***collecting a sample of the fluid with a brush having flexible bristles***. In claim 6, applicant claims a method of detecting blood in fecal material. The method includes the steps from claim 1, but applicant also specifies the fluid to be water and adds the step of detecting any blood which may be present in the fluid sample. The Examiner did not find prior art which teaches or suggests the method steps. The Examiner considers "Kayaga" to be the closest prior art. Kayaga teaches the collection of solid stool samples with a sampling brush, but does not teach the sampling of liquid samples.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

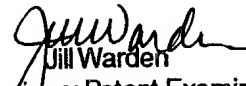
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
August 5, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700